

Comparative evaluation of apical pressure generated by EDDY, GentleWave G4, and passive ultrasonic irrigation: A 3D-printed root canal model

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Abstract

Aim: This in vitro study compared the mean and peak apical pressures generated by EDDY, GentleWave G4, and passive ultrasonic irrigation (PUI) in a standardized 3D-printed root canal model.

Methodology: A standardized straight root canal model (apical diameter 0.25 mm, 4% taper, 16 mm working length) was fabricated by resin-based stereolithographic printing. Apical pressure was measured with a validated setup comprising a piezoresistive pressure transducer (PXM409-350; Omega), a DAQ board (USB6008; National Instruments), and LabVIEW software. Distilled water served as the irrigating medium. Twenty measurements were performed per group (n=20, 60 total), with each recording 12,020 data points over 12 seconds. EDDY was activated with a TA-200 air scaler (power level 2, #25/.04 tip); GentleWave G4 was operated per the manufacturer's protocol; and PUI was performed with a Newtron P5 XS ultrasonic unit (power level 6, IrriSafe #20 tip, 2 mm short of the working length). Normality was confirmed by the Shapiro-Wilk test, and group comparisons were performed using Welch ANOVA with Games-Howell post hoc comparisons. The study followed PRILE 2021 reporting guidelines.

Results: Significant differences were observed across all groups for both mean and peak apical pressures ($p < 0.001$). EDDY produced the highest mean (16.03 ± 4.04 mmHg) and peak (35.53 ± 2.84 mmHg) apical pressures, exceeding the safety threshold in every measurement. GentleWave G4 yielded a negative mean apical pressure (-15.60 ± 7.96 mmHg) and a mean peak of 8.00 ± 6.76 mmHg, remaining below the threshold throughout. PUI generated near-zero mean apical pressure (-0.07 ± 0.05 mmHg) and a mean peak of 2.27 ± 0.05 mmHg, consistently below the critical threshold. All pairwise comparisons were significant ($p < 0.001$), including GentleWave G4 vs. PUI for peak pressure ($p = 0.003$).

Conclusion: GentleWave G4 and PUI produced apical pressures below the established safety threshold, whereas EDDY exceeded it in all measurements, indicating a higher risk of periapical irrigant extrusion. Further ex vivo and in vivo studies with anatomically complex geometries are warranted.

Keywords: Apical pressure, endodontic irrigation, GentleWave G4, irrigant extrusion, sonic activation, PUI

Introduction

Sodium hypochlorite (NaOCl) remains the irrigant of choice in endodontics for its potent antimicrobial activity and ability to dissolve organic tissue (1). However, extrusion of NaOCl beyond the apical foramen can cause severe complications, including immediate pain, extensive soft-tissue swelling, ecchymosis, and potentially irreversible neurological damage (2). A systematic review of 52 documented cases found that such accidents occur predominantly in maxillary teeth and in female patients, with symptoms appearing within minutes and full recovery often requiring several weeks (2). An anatomical review proposed that apically directed positive pressure may infuse NaOCl into the facial venous system via non-collapsible intraosseous sinusoids, explaining the characteristic panfacial ecchymosis pattern observed regardless of tooth location (3).

Apical fluid pressure has been established as the principal determinant of irrigant extrusion risk (4, 5). Park et al. (4) developed an in vitro measurement model using a piezoresistive pressure transducer mounted in an airtight chamber, demonstrating that positive apical pressure increases non-linearly with flow rate and readily exceeds capillary blood pressure at clinically relevant delivery rates. Khan et al. (5) subsequently used a polycarbonate root canal model to measure the pressure generated by five canal irrigation devices, finding that all positive-pressure systems exceeded the central venous pressure (CVP) of 5.88 mmHg at flow rates above 1 mL/min. Only the EndoVac (Discus Dental, LLC, Culver City, CA, USA) negative-pressure system remained consistently below this threshold. The critical safety threshold of 5.73 mmHg (the lower limit of CVP) introduced in that study has since served as the reference criterion in apical pressure research (5). Importantly, Hülsmann and Hahn (6) emphasized that irrigant extrusion may occur even without needle binding, as sufficient apical pressure can be generated under routine clinical irrigation conditions.

Several irrigant activation systems have been developed as alternatives to conventional syringe-needle irrigation, each employing distinct fluid-dynamic mechanisms (1). Passive ultrasonic irrigation (PUI) enhances irrigant penetration through acoustic streaming and cavitation generated by an ultrasonically activated metal tip (1). EDDY (VDW GmbH, Munich, Germany) is a sonic activation device driven by an air scaler operating at approximately 6,000 oscillations per second; its polyamide tip produces a wide oscillation amplitude while minimizing the risk of instrument fracture (1, 7). The GentleWave G4 system (Sonendo Inc., Laguna Hills, CA, USA) operates on a multisonic negative-pressure principle, delivering degassed irrigant at high velocity through a handpiece placed on the tooth while simultaneously evacuating fluid and debris. It requires minimal canal preparation (8).

Despite the clinical relevance of these three systems, no study has directly compared EDDY,

GentleWave G4, and PUI under identical experimental conditions using a standardized 3D-printed canal model and a validated pressure acquisition system. Thus, the aim of this in vitro study was to compare the mean and peak apical pressures generated by EDDY, GentleWave G4, and PUI using a standardized 3D-printed root canal model and a validated pressure transducer setup. The null hypothesis was that there would be no statistically significant difference in mean apical pressure among the three irrigation activation systems.

Material and Methods

Study design and ethical compliance

This laboratory study was conducted in accordance with the 2021 Preferred Reporting Items for Laboratory Studies in Endodontology (PRILE) guidelines (9). No human or animal subjects were used; all experiments were performed on standardized 3D-printed root canal models. Therefore, no ethical approval was required.

Sample size calculation

The sample size was determined a priori using G*Power (version 3.1.9.7; Heinrich-Heine-Universität, Düsseldorf, Germany). For a one-way ANOVA comparing three groups with $\alpha = 0.05$, a power (1– β) of 0.90, and a large effect size (Cohen's $f = 0.50$) assumed from the magnitude of device- and geometry-related apical pressure differences reported in a comparable study (8), a minimum of 18 measurements per group was required. Accordingly, 20 measurements per group (60 in total) were obtained. The primary outcome was mean apical pressure, and peak apical pressure was the secondary outcome.

Eligibility and 3D modeling

Root canal models with an apical diameter of 0.25 mm and a standard 4% taper were selected as the reference geometry, with a canal length of 16 mm (Fig. 1). Digital designs were created in Shapr3D (Version 5.1013.0.10157, Shapr3D Zrt., Budapest, Hungary) and exported as STL files. The STL files were printed on a stereolithography resin printer (Photon Mono 4 Ultra; Anycubic Technology Co., Ltd., Shenzhen, China) at an XY resolution of $17 \times 17 \mu\text{m}$ and a Z-axis accuracy of $20 \mu\text{m}$. A transparent, high-clarity resin (Anycubic) was used to allow visual inspection and video documentation of irrigation. Each printed model was washed in 99% isopropyl alcohol for 15 minutes and then post-cured for 30 minutes in a curing unit. The apical diameter of each printed model was verified under a dental operating microscope (Zumax OMS 3200; Zumax Medical Co., Ltd., Suzhou, China) and measured using ImageJ software (NIH, Bethesda, MD, USA).

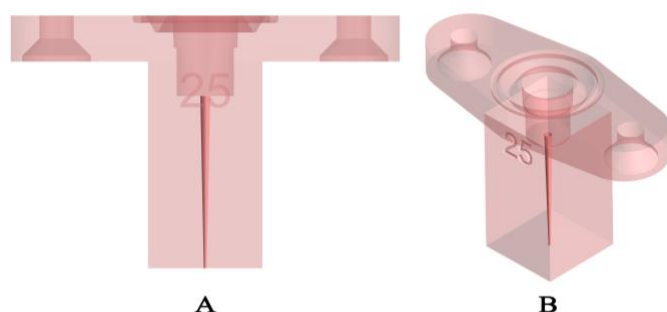


Figure 1. (A) Cross-sectional view of the 3D-designed transparent root canal model illustrating the standardized canal geometry. (B) Three-dimensional perspective view of the model.

Three transparent replicas were produced ($n = 1$ per group). Each was tagged with a unique identification code, group allocation was concealed from the data analyst, and operator blinding was not feasible because the three irrigation devices are physically distinguishable.

Apical pressure measurement setup

The apical pressure measurement setup used in the present study was based on methods described by Park et al. (4) and Haapasalo et al. (8). Each resin model was placed in an airtight custom fixture filled with distilled water and coupled to a piezoresistive pressure transducer (PXM409-350; Omega Engineering Inc., Stamford, CT, USA). The apical end of the model canal was left patent to allow pressure transmission, while other openings were sealed with hot glue to ensure a closed measurement system. Pressure generated at the apical region during irrigation was transmitted through the incompressible fluid to the transducer. The transducer's electrical current output (mA) was converted to voltage (V) using a resistor and a data acquisition (DAQ) board (USB6008; National Instruments Corp., Austin, TX, USA). Voltage readings were then converted to pressure values (mmHg) in LabVIEW (National Instruments Corp., Austin, TX, USA) using the calibrated pressure transducer's sensitivity coefficient.

Calibration was performed by connecting the fixture to a calibrated analog pressure gauge via a Luer fitting and a tooth mount. A syringe filled with distilled water was used to generate incremental pressures within the fixture, and readings from the LabVIEW-based setup were compared with the analog gauge at 1-psig increments from 0 psig (0 mmHg) to 5 psig (258 mmHg). Additionally, hydrostatic pressure was measured at 5 water column heights and compared with theoretical values, yielding a linear correlation coefficient of 0.9997 and confirming the accuracy and repeatability of the measurement system.

Distilled water was used as the irrigation medium for all pressure measurements because its flow properties are equivalent to those of sodium hypochlorite, as reported in previous studies (4, 8).

Experimental groups

GentleWave G4 System

The GentleWave G4 system (Sonendo Inc., Laguna Hills, CA, USA) was operated via a CleanFlow handpiece (Sonendo Inc., Laguna Hills, CA, USA). A customized occlusal platform was fabricated from the resin material SoundSeal to ensure an airtight seal between the handpiece (Sonendo Inc., Laguna Hills, CA, USA) and the access cavity. The GentleWave console generated irrigant delivery and fluid dynamics at a flow rate of 45–50 mL/min. The GentleWave G4 console delivered distilled water, and the irrigation protocol lasted 485 s.

Sonic Irrigation System

The EDDY tip (#25/.04, VDW GmbH, Munich, Germany) was used with an air scaler (TA-200; Micron Co., Ltd., Tokyo, Japan) at power setting 2. The tip was placed 2 mm short of the working length. The activation was performed in cycles of 10 seconds of delivery and 10 seconds of activation. These sustained cycles allowed for regular irrigant replenishment during sonic activation. The customized irrigation pump (2 mL/min) ensured continuous delivery during the activation phases to standardize delivery.

Passive Ultrasonic Irrigation (PUI)

An ultrasonic device (Newtron P5 XS; Satelec Acteon, Merignac-Cedex, France) with an IrriSafe tip (#20/21mm, Satelec Acteon, Merignac-Cedex, France) was used in dynamic motion of 2 mm push-pull amplitude (power setting: 6). To deliver distilled water continuously, the irrigation pump was used at 2 mL/min. The maximum tip penetration for the working length was 2 mm coronal to the apex, and each irrigation cycle lasted 20 s, including 10 s for continuous flushing and 10 s for activation. These irrigation cycles were repeated for a total of 485 s.

Apical pressure measurement protocol

Before each measurement, the irrigation device was positioned, and the system was allowed to stabilize until apical pressure readings reached baseline. Each irrigation system was operated according to the manufacturer's recommended protocol. Although the full clinical activation protocol lasts 485 s, for each measurement data were acquired over a representative 12-second period, during which 12,020 pressure data points were recorded. The mean apical pressure was calculated as the average of all data points within this window, and the peak apical pressure was defined as the maximum instantaneous pressure recorded during the window. Each irrigation system was evaluated on a single standardized model, on which 20 independent runs were performed (20 measurements per group), yielding a total

of 60 apical pressure measurements across all three groups. Between consecutive measurements, the system was allowed to return to baseline before the next recording was initiated. All measurements were performed sequentially for each system by a single operator with 15 years of clinical endodontic experience. Representative pressure-time profiles for each system are provided as Figure 2.

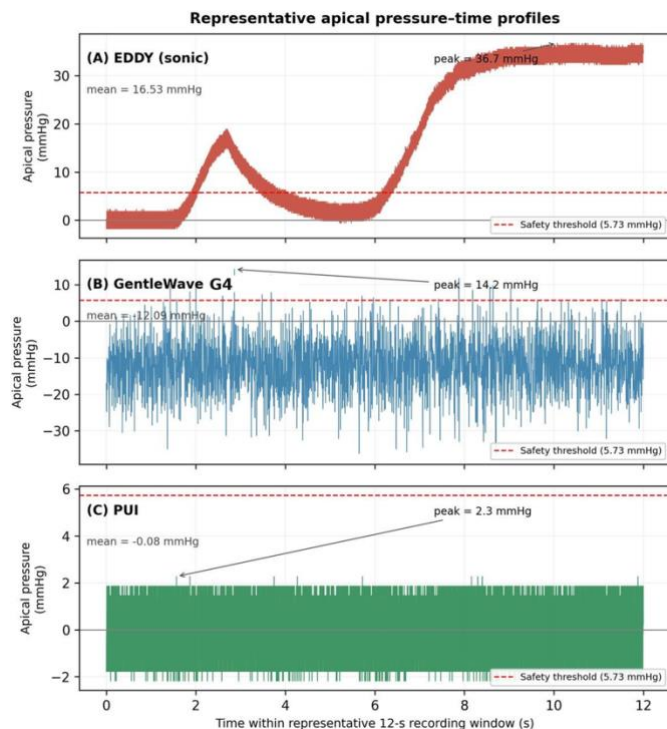


Figure 2. Pressure-time profiles for each system.

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics (version 29.0; IBM Corp., Armonk, NY, USA). The Shapiro-Wilk test confirmed normality across all groups and variables ($p > 0.05$ for all), supporting the use of parametric tests. Levene's test revealed a significant violation of the equal-variance assumption for both mean

($F = 19.60$, $p < 0.001$) and peak ($F = 22.61$, $p < 0.001$) apical pressure.

Welch's analysis of variance (ANOVA), which does not assume homogeneity of variances, was used to compare mean and peak apical pressures across the three irrigation systems, with significance set at $p < 0.05$. Post hoc pairwise comparisons were conducted using the Games-Howell test. Effect sizes were expressed as η^2 for the omnibus comparisons and Hedges' g for pairwise comparisons. Results are reported as mean $\pm$ standard deviation (SD). The critical apical pressure threshold of 5.73 mmHg, as established by Khan et al. (5), served as the reference for interpreting clinical safety.

Results

The mean and peak apical pressure values for all three irrigation systems are shown in Table 1. The Shapiro-Wilk test confirmed normality across all groups and variables ($p > 0.05$ for all). Welch's ANOVA showed statistically significant differences among the three irrigation systems for both mean apical pressure [$F(2, 25.34) = 192.21$, $p < 0.001$, $\eta^2 = 0.87$] and peak apical pressure [$F(2, 25.34) = 1343.63$, $p < 0.001$, $\eta^2 = 0.93$].

For mean apical pressure, EDDY produced the highest positive values (16.03 ± 4.04 mmHg), substantially exceeding the critical safety threshold of 5.73 mmHg in all 20 measurements (Fig. 3). In contrast, GentleWave G4 produced consistently negative mean apical pressures (-15.60 ± 7.96 mmHg), whereas PUI produced values near zero (-0.07 ± 0.05 mmHg). Games-Howell post hoc analysis revealed statistically significant differences between EDDY and GentleWave G4 ($p < 0.001$), EDDY and PUI ($p < 0.001$), and GentleWave G4 and PUI ($p < 0.001$).

A similar pattern was observed for peak apical pressure (Fig. 4). EDDY produced the highest peak values (35.53 ± 2.84 mmHg), which far exceeded the safety threshold across all measurements. GentleWave G4 generated substantially lower peak pressures (8.00 ± 6.76 mmHg), and PUI produced the lowest and most consistent peak values (2.27 ± 0.05 mmHg). All pairwise comparisons remained statistically significant in the Games-Howell test (EDDY vs GentleWave G4: $p < 0.001$; EDDY vs PUI: $p < 0.001$; GentleWave G4 vs PUI: $p = 0.003$).

Table 1. Mean and peak apical pressures (mmHg) produced by the EDDY sonic irrigation system, the GentleWave G4 multisonic system, and passive ultrasonic irrigation (PUI) in standardized 3D-printed root canal models.

Irrigation System	Mean Apical Pressure (mmHg)					Peak Apical Pressure (mmHg)			
	n	Mean $\pm$ SD	95% CI	Min	Max	Mean $\pm$ SD	95% CI	Min	Max
EDDY	20	16.03 ± 4.04^a	14.14 to 17.92	8.71	23.39	35.53 ± 2.84^a	34.20 to 36.86	28.92	39.60
GentleWave G4 System	20	-15.60 ± 7.96^b	-19.33 to -11.87	-29.53	1.82	8.00 ± 6.76^b	4.83 to 11.17	-6.09	22.70
PUI	20	-0.07 ± 0.05^b	-0.09 to -0.05	-0.18	-0.01	2.27 ± 0.05^b	2.25 to 2.29	2.18	2.39

^{a, b}: Different superscript letters indicate statistically significant difference between groups (Games-Howell post-hoc, $p < 0.05$).

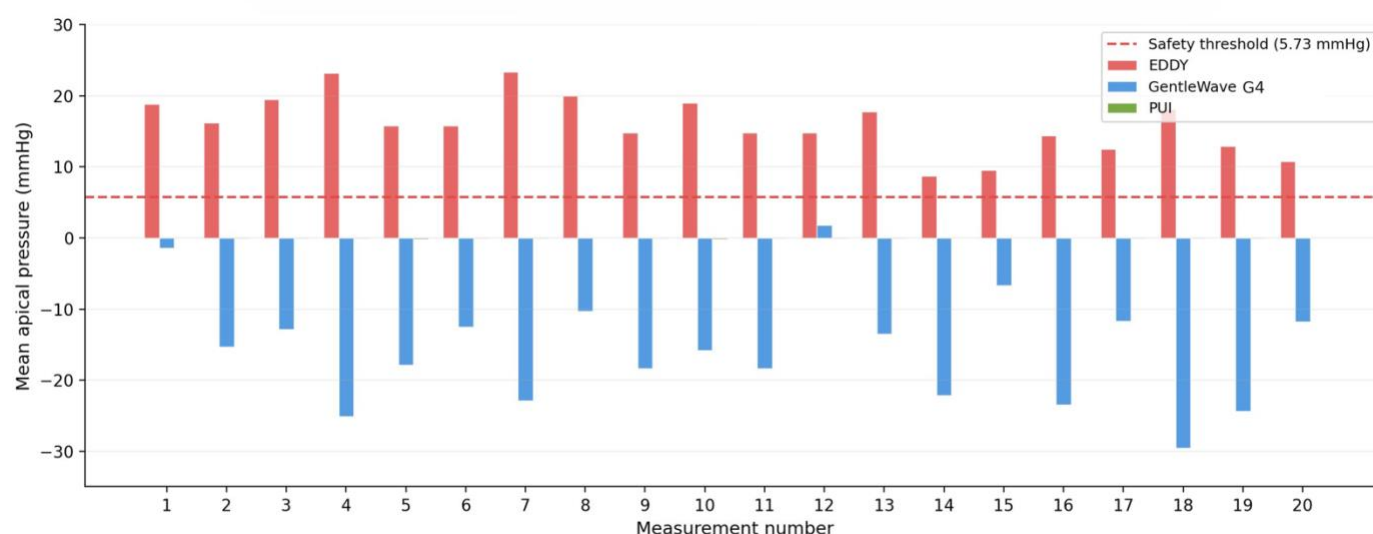


Figure 3. Mean apical pressure (mmHg) recorded over 20 consecutive measurements for each irrigation system. Each bar represents a single measurement. The dashed red line marks the critical apical pressure safety threshold of 5.73 mmHg. EDDY consistently generated positive mean apical pressures exceeding this threshold across all measurements, whereas GentleWave G4 produced negative apical pressures, and PUI remained near zero throughout.

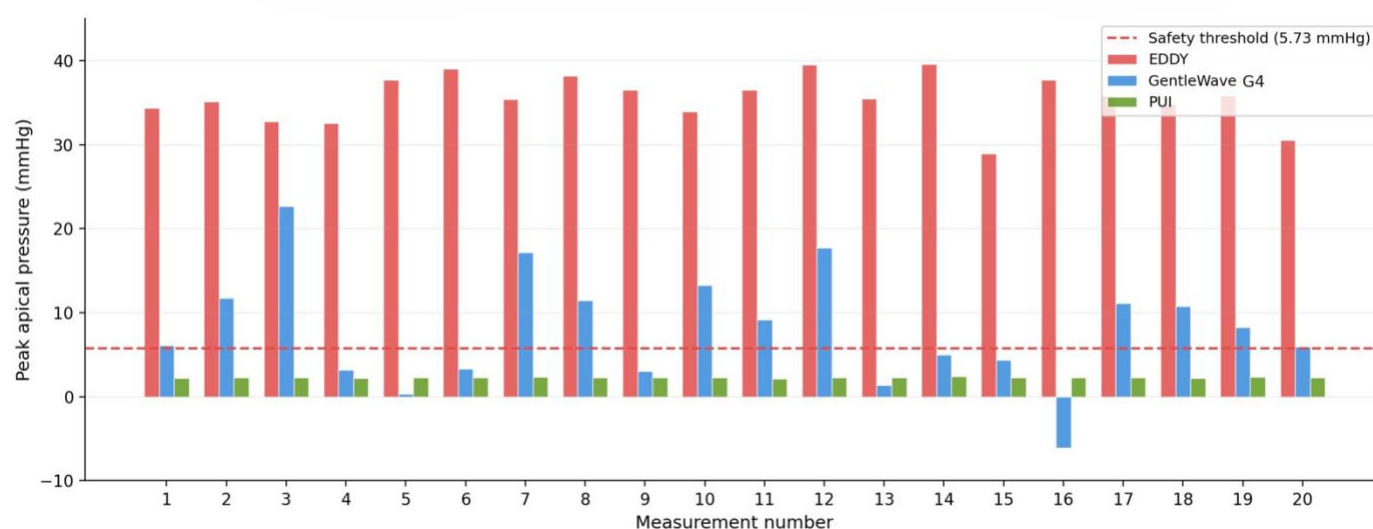


Figure 4. Peak apical pressure (mmHg) recorded across 20 consecutive measurements for each irrigation system. Each bar represents the maximum pressure in a 12-second recording. The dashed red line indicates the critical apical pressure safety threshold of 5.73 mmHg. EDDY peak values consistently and substantially exceeded the safety threshold, whereas GentleWave G4 and PUI remained below or near this reference value.

Discussion

This in vitro study compared the apical pressures generated by EDDY, GentleWave G4, and PUI using a standardized 3D-printed root canal model and a validated pressure-acquisition setup. The null hypothesis was rejected, as statistically significant differences were observed among all three groups for both mean and peak apical pressures ($p < 0.001$).

GentleWave G4 consistently generated negative mean apical pressure (-15.60 ± 7.96 mmHg), remaining below the 5.73 mmHg safety threshold across all measurements. This finding aligns with previous studies evaluating earlier iterations of the GentleWave system (8). Haapasalo et al. (8) reported negative apical pressures ranging from -13.07 to -17.19 mmHg in maxillary molars, regardless of instrumentation level, using the same pressure-transducer setup as in the present study. Ordinola-Zapata et al. (10) confirmed a mean negative pressure of -30.79 mmHg in mandibular

molars, and Chen et al. (11) demonstrated that this profile was maintained across apical sizes from #10 to #110. The negative apical pressure generated by the GentleWave system is attributable to its built-in suction mechanism, which creates a pressure gradient directed away from the periapex and simultaneously evacuates irrigant, debris, and dissolved tissue (8, 12). An earlier study by Charara et al. (13) further confirmed that no apical extrusion occurred during GentleWave irrigation, even in simulated apical environments with enlarged foramina. However, the referenced pressure studies evaluated earlier versions of the GentleWave platform, whereas the present study used the GentleWave G4 with its updated handpiece design and delivery protocol; direct quantitative comparisons should therefore be interpreted with caution.

EDDY generated the highest mean apical pressure among the three systems (16.03 ± 4.04 mmHg), exceeding the 5.73 mmHg safety threshold in all measurements, with peak values reaching 35.53 ± 2.84 mmHg. These results align with Magni et al. (14), who reported that EDDY applied at tooth length exceeded the critical threshold in 100% of measurements in a 3D-printed open-apex incisor model. The present study extends those findings to a standardized closed-apex geometry, confirming that EDDY's positive-pressure risk is not confined to immature teeth. The mechanism underlying EDDY's elevated apical pressure likely relates to its sonic oscillation dynamics: the polyamide tip oscillating at approximately 6,000 cycles per second generates fluid acceleration directed toward the apical terminus, which, in a closed or semi-closed apical environment, translates into measurable positive pressure (1, 7). Computational fluid dynamics studies have demonstrated that positive-pressure systems create apically directed pressure gradients that increase substantially with insertion depth and flow rate (15-17), and the present findings suggest that EDDY's sonic mechanism produces analogous effects. Consistent with these pressure data, Ince Yusufoglu et al. (7) documented significantly greater apical debris extrusion with EDDY compared to PUI, PIPS, and manual irrigation in curved mandibular molars ($p < 0.001$), while Karasu et al. (18) reported greater NaOCl extrusion with EDDY in immature teeth. Neuhaus et al. (19) confirmed EDDY's antibacterial efficacy, and Haupt et al. (20) demonstrated favorable smear layer removal performance; however, the present findings indicate that this cleaning capacity is accompanied by an apical pressure profile that warrants clinical caution. Psimma et al. (21) showed that irrigant extrusion may occur even without needle binding when apical pressure is sufficient, and Hülsmann and Hahn (6) similarly emphasized that irrigation-related complications may arise under routine clinical conditions. These considerations are particularly relevant in clinical scenarios involving open apices, periapical lesions, or thin cortical bone (conditions recognized as predisposing factors for hypochlorite accidents), where apical pressure exceeding the CVP threshold poses a tangible risk of extrusion (2, 3, 22).

PUI produced a near-zero mean apical pressure (-0.07 ± 0.05 mmHg) that remained below the safety threshold in all measurements, with peak values of only 2.27 ± 0.05 mmHg. This favorable pressure profile aligns with the fluid dynamic principles underlying PUI. Unlike positive-pressure delivery systems, the ultrasonically activated file oscillates freely within the canal without directing irrigant flow apically under pressure; instead, acoustic streaming distributes the irrigant laterally and coronally (1, 23). Khan et al. (5) demonstrated that systems generating pressures below the CVP threshold of 5.88 mmHg (derived from established venous pressure measurements) pose a considerably lower risk of extrusion (24-25). The near-zero pressure observed for PUI supports its classification as a low-risk activation modality regarding periapical pressure. Gu et al. (26) categorized PUI as one of the most widely adopted activation techniques in contemporary endodontics, and van der Sluis et al. (23) highlighted its capacity to enhance irrigant penetration into lateral canals and isthmuses without generating hazardous apical pressures. Nevertheless, lower apical pressure does not necessarily equate to superior debridement; the clinical selection of an activation system must balance safety with cleaning efficacy across the full complexity of root canal anatomy (1, 12, 27).

The 3D-printed resin canal model used in this study provided critical methodological advantages. Standardized canal geometry (apical diameter 0.25 mm, 4% taper, 16 mm length) eliminated the confounding influence of anatomical variability inherent in extracted human teeth, ensuring that observed pressure differences were attributable solely to the irrigation system (4, 28). Anderson et al. (28) highlighted that 3D printing enables the production of highly reproducible endodontic models with clinically relevant geometries, and the present workflow (incorporating computer-aided design via Shapr3D and resin-based stereolithographic printing) operationalized this principle. The pressure acquisition setup, validated by Haapasalo et al. (8) with $R^2=0.9997$ and subsequently employed by Park et al. (4), Chen et al. (11), and Ordinola-Zapata et al. (10), provided continuous, high-resolution data (12,020 data points per 12-second measurement), enabling robust analysis of both mean and peak pressures. The use of distilled water as the irrigating medium, rather than NaOCl, is a methodological precedent established by Park et al. (4) and Haapasalo et al. (8), who demonstrated no statistically significant difference in apical pressure between the two solutions.

Several limitations merit consideration. First, the 3D-printed resin model does not replicate the viscoelastic properties of dentinal tissue or the periapical microenvironment, including the periodontal ligament and vascular elements that would modulate pressure dissipation in vivo (4, 12). Second, each group comprised a single standardized model with 20 repeated measurements rather than 20 independent specimens. While this design maximizes geometric consistency and is analogous to approaches adopted by Haapasalo et al. (8) and Chen et al. (11), it limits generalizability across

different canal configurations. Huang et al. (29) demonstrated that canal anastomoses may substantially reduce apical pressure build-up, suggesting that molar anatomy with isthmuses could produce different pressure dynamics than the straight single-canal model used here. Third, the present study evaluated a straight canal geometry; Psimma et al. (21) noted that canal curvature may influence irrigant extrusion dynamics, and further research using anatomically complex geometries is warranted. Fourth, direct quantitative comparison with previous GentleWave pressure data is limited using the G4 platform, which differs from the systems evaluated in the referenced studies (8, 10).

Within the limitations of this in vitro study, the results demonstrate that GentleWave G4 and PUI consistently generated apical pressures below the established safety threshold, whereas EDDY exceeded it in all measurements. Within the straight, single-canal geometry and the specific protocol parameters evaluated, these findings may help inform irrigation system selection in clinically sensitive scenarios and highlight the importance of evaluating apical pressure alongside debridement efficacy when assessing irrigation activation methods; their generalizability to curved or multi-canal anatomy and to other protocols remains to be confirmed.

Disclosures

Peer-review: Externally peer-reviewed.

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